

The Biomet® EBI Bone Healing System

Physician Manual and Package Insert
English Language



BIOMET®
BONE HEALING

Powered by **EBI** Technology

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Important Safeguards and Contents

Read All Instructions Before Using

When using electrical products, basic safety precautions should always be observed:

! WARNING: To reduce the risk of electric shock, fire or potential injuries please adhere to the following:

- 1. Do not use your bone healing system while bathing.
- 2. Do not place or store your bone healing system where it can fall or be pulled into a tub, sink or any pool of liquid.
- 3. Do not immerse or drop your bone healing system's control unit, treatment coil, AC Wall Adapter, in any liquid.
- 4. Do not reach for your bone healing system that has fallen into a liquid. Unplug from the wall outlet immediately.
- 5. Do not permit the AC Wall Adapter to be connected when wet.
- 6. Never touch the AC Wall Adapter contacts when the AC Wall Adapter is plugged into an AC Wall outlet.
- 7. Do not place the AC Wall Adapter in the bed with you if you are treating while you are sleeping.
- 8. Never operate your bone healing system if it has a damaged link cable, cord or plug, if it is not working properly, if it has been dropped and damaged, or immersed into any liquid. Contact Biomet immediately for a replacement part(s).
- 9. Keep all electrical cords and cables away from heated surfaces.
- 10. Keep all electrical cords and cables away from children.
- 11. Never insert any object into any opening of your bone healing system.
- 12. Do not place your bone healing system's control unit in prolonged heat or direct sunlight. (Normal operating temperature range is 5°C to 38°C,[41°F to 100°F], 20-80% RH non-condensing, normal

storage/transport temperature is -15°C to 60°C [5°F to 140°F].)

- 13. Use your bone healing system only for its intended use as prescribed by your physician and described in this manual.
- 14. No modification to this device is allowed for any reason whatsoever.
- 15. Routine use of bone healing systems for over 30 years has demonstrated that any known hazard associated with their use does not present an unreasonable risk of illness or injury when compared to the benefit of their use.
- 16. Use of your bone healing system for the spine and skull has not been evaluated or approved.

***NOTE:** Please contact the Biomet Patient Support Department in Parsippany, New Jersey between the hours of 8:30 a.m. and 5:30 p.m. Eastern Time at 1.973.299.9300 with any questions or problems.

SAVE THESE INSTRUCTIONS

Contents – Biomet® EBI Bone Healing System

- Control unit/Controller
- Connector cables (0" and 28")
- Belt
- Clip Holder
- AC Wall Adapter
- User Manual and Package Insert
- Carrying case

CAUTION: Rx Only Federal Law (U.S.A.) restricts this device to sale by or on the order of a physician. For Prescription Use Only. Single prescription. Single patient use. Not for re-sale.

Please note: This system does not contain a treatment coil. Please contact your Biomet/ EBI representative for the specific anatomically correct treatment coil.

***NOTE:** The Control Unit must not be worn on the coil.

SFLX Treatment Coil

Description

The Biomet® EBI Bone Healing System promotes healing by inducing weak pulsing electrical currents at the fracture nonunion site. These signals are generated by a low energy electromagnetic field created by passing specific current pulses through an anatomically configured treatment coil.

Electrical Requirements of AC Wall Adapter Unit – USA/Americas

Input: 100 – 240V \sim 50 – 60Hz 0.3-0.8 A

Output: 12V \equiv @2.0A MAX

Do not use any other AC wall adapter with the Biomet® EBI Bone Healing System.

Electrical Requirements

The Biomet® EBI Bone Healing System Control unit is available in the following configuration.

Americas

- Includes an AC Adapter charger with a standard two prong plug

***NOTE:** An International Wall Plug Blade Adapter Kit is available for patients who will be traveling outside the US and wish to continue their treatment while abroad.

System Components

Control Unit – Controller

The Biomet® EBI Bone Healing System control unit operates on a permanently installed lithium ion, rechargeable battery which facilitates ambulatory use. The control unit contains solid state electronics programmed to operate the SFLX family of Treatment Coils. It includes an audible and visible self checking alarm mechanism to alert the patient if the unit is not functioning properly.

***NOTE:** The control unit can not be used with the FLX® family of Treatment Coils used with the EBI Bone Healing System® - Model 2001.

The control unit is designed to store the patient's daily treatment information. Patients are recommended to bring the control unit and treatment coil to each follow-up visit to provide the opportunity to review their overall treatment compliance in how they are using their Biomet® EBI Bone Healing System.

***NOTE:** While walking, the patient may wear the control unit comfortably on a belt or the waist using the Clip Holder.

Battery Charger/AC Wall Adapter

1. The AC Wall Adapter is designed to recharge the permanently installed battery inside the control unit. (See step 3: Treating and Charging – page 9)
2. The control unit allows for treating while charging.

Do not use any other AC Wall Adapter with the Biomet® EBI Bone Healing System.

Link Cable

The link cable connects the control unit to its SFLX Flexible Treatment Coil. The link cables supplied are “zero” and 28” cables. An optional

link cable is also available in a 48” length. For a 48” cable, call the Biomet Patient Support Department at 1.973.299.9300. Outside the United States contact your local EBI/Biomet Distributor.

SFLX Flexible Treatment Coil

The SFLX Flexible Treatment Coil is an encased wire coil that may be incorporated into a cast, over a cast or brace, or when a cast is not utilized, may be applied directly onto the skin. A specific electrical current is delivered to the coil by the control unit. The coil then delivers the therapeutic electromagnetic signal to the fracture nonunion site.

***NOTE:** The SFLX Coil is not included with the system assembly and will be provided separately by your Biomet sales representative.

***NOTE:** The Control Unit must not be worn on the coil.



Full Prescribing Information

The mechanism of action behind the PEMF technology involves the upregulation of factors that modulate normal bone healing. PEMF increases a number of factors such as TGF- β 1, BMP-2 and BMP-4, which are normal physiological regulators of the various stages of bone healing, including angiogenesis, chondrogenesis and osteogenesis.

Intended User Profile

The EBI Bone Healing System® is intended to treat adults who have been medically diagnosed with a fracture nonunion or failed fusion in the appendicular system. It is also intended to treat congenital pseudarthrosis in the appendicular system in pediatric patients not skeletally mature.

Indications for Use

The Biomet® EBI Bone Healing System is indicated for the treatment of fracture nonunions, failed fusions, and congenital pseudarthrosis in the appendicular system. A nonunion is considered to be established when there are no visibly progressive signs of healing.

The original 1979 PMA study included 146 patients with nonunion fractures. These difficult fractures were characterized as follows: 2.3 average number of prior surgeries and an average of thirty-seven months (median twenty months) since original injury. These patients were followed for a minimum of four years (average seven years) from the date of treatment termination, with a success rate of 63.5%. Even though long term follow-up requirements were not included in the original study designs, a follow-up rate of 82% was achieved. Forty-three (43) of the original 48 patients in the congenital pseudarthrosis study were classified by Bassett¹ who defined the tibial lesions as Type I (n=6), Type II (n=19) and Type III (n=18), with Type III being the

most severe and recalcitrant to treatment. The success rate for Bassett Type I lesions was 66.7%, Bassett Type II lesions 57.9% and Bassett Type III lesions 22.2%. The long term post treatment follow-up for the congenital pseudarthrosis study patient population (n=48) was to skeletal maturity or the age of 18. The study had an 87.5% follow-up rate.

1. Bassett CAL, N Caulo and J Kort, "Congenital pseudarthrosis of the tibia: Treatment with pulsing electromagnetic fields". Clinical Orthop, 154: 136-149, 1981.

Contraindications

- A. Nonunion fractures in which a synovial pseudarthrosis (fluid filled gap) exists.
- B. Under certain conditions, electromagnetic stimulation could inhibit or impair the functioning of certain external, non-invasive and/or implanted, invasive active medical devices inclusive of "all active electrical and non-active conductive/metallic implants" as well as "worn medical devices" due to adverse events that may occur with other active electrical implants (e.g., Spinal Cord stimulators, Implantable Cardioverter-defibrillators, etc.) The impact or effect of pulsed electromagnetic fields generated by a non invasive bone growth stimulator on the function of other anatomical stimulators, pain pumps, insulin pumps, implanted spinal nerve stimulators and similar active devices has not been evaluated.



- C. Use of the Biomet® EBI Bone Healing System on pregnant patients has not been evaluated; therefore, it is not recommended in these cases.



- D. The Biomet® EBI Bone Healing System has not been tested for safety or been evaluated for heating in the MR environment. The effects of MRI procedures and scans using MR systems has not been determined or established: therefore, MRI scans and procedures should not be performed on patients until the device system has been completely removed.



MR Unsafe- Not for MRI Use

Warnings

- A. The long term effects of exposure to low level magnetic fields are not known. Routine use of the bone healing system devices for over 30 years has indicated no known risks.
- B. During the treatment of patients with open epiphyses, when the epiphysis is in the pulsing field, physicians are advised that the epiphyseal growth plates should be monitored for possible effects.
- C. Use of the Biomet® EBI Bone Healing System for the spine and skull have not been evaluated.
- D. To reduce the risk of potential injury:
1. AVOID touching the AC Wall Adapter contacts when the AC Wall Adapter is plugged into an AC outlet.
 2. DO NOT charge the battery in bed if treating while sleeping.
- E. The control unit is electrically live when connected with the AC Wall Adapter and plugged into an outlet. To reduce the risk of serious injury by electric shock patients are

advised:

1. DO NOT permit the AC Adapter to be connected when wet.
2. DO NOT immerse the control unit, treatment coil, or the AC Wall Adapter in any liquid.

Precautions

The following conditions may compromise a successful treatment outcome.

- A. Nonunion fractures with gaps in excess of 1.0 cm.
- B. Presence of fixation devices or instrumentation made from magnetic materials.

Please note: Most presently used internal or external fixation devices are constructed of 316L S.S., titanium alloys, and cobalt-chromium alloys which are non-magnetic and, therefore, compatible with the Biomet® EBI Bone Healing System.

Adverse Effects

Based upon an historical adverse event report review composed of Medical Device Reports – MDRs identified within the FDA Manufacturer and User Facility Database for similar, relevant devices, the probability of experiencing an adverse event when using a Bone Healing System is extremely unlikely, or less than 1% (.0133%).

The database, although imprecise is intended to provide and present a general summary of product-specific event data that manufacturers, user facilities and distributors provide to the FDA based upon relevant product codes for similar devices.

The original EBI Bone Healing System was approved and introduced in 1979. Since then, over 600, 000 systems have been marketed. The safe and effective use of non-invasive bone growth stimulation devices over this time has clearly established their therapeutic benefit of use. In addition, all known hazards associated with the use of Bone Healing Systems do not present an unreasonable risk of illness or injury when compared to their therapeutic benefit and can be typically addressed by either modifying or terminating treatment.

General Treatment Instructions

Recommended Usage

The recommended daily treatment dosage is normally 10 hours per day.

Although the device was shown to be effective at treatment times between 3 to 10 hours per day, a review of the clinical data has shown that healing may occur earlier when treatment is achieved at the recommended 10 hours per day.

Compliance with the recommended ten (10) hours per day treatment is very important. A review of the clinical data demonstrates that less than the recommended use of this device possibly results in an increase in the time to heal your fracture. If you are unable to treat for ten continuous hours, it is recommended that you break up the total treatment time into more than one session. Please refer to the following General Treatment Instructions.

General Treatment Instructions

Treatment should not be suspended until healing occurs or until such time as the prescribing physician recommends discontinuation of the device.

The Biomet® EBI Bone Healing System is programmed to deliver a maximum of 270 therapeutic treatment periods. Biomet recommends a therapeutic treatment period of 10 hours per day. A therapeutic treatment period is defined as a 10 hour treatment session accomplished either continuously or discontinuously in segments totaling 10 hours.

• Unsegmented Continuous Treatment Period:

Patient wears the device with coil in place for 10 consecutive hours without interruption

• Segmented Discontinuous Treatment Period

(Example): Patient treats with coil in place for four hours, turns the device off and does not push the RESET button. Patient then turns the device on within the next 12 hours and only

completes the remaining six hours of treatment for that therapeutic treatment period.

• Shortened Segmented:

A treatment period of less than 10 hours may be achieved by pushing the reset button prior to the completion of the 10-hour period. Once the device has been reset, the system software will reset the controller to start a new treatment period.

• Shortened Segment Treatment Period

(Example): Patient completes eight hours of treatment with coil in place and then turns device off. Less than 12 hours later, the patient turns device on and pushes RESET button. Patient received eight hours of treatment and controller is set to treat for a full 10 hours. Patient compliance usage log is credited with eight hours.

All hours treated will be electronically recorded and stored within the controller. Patients unable to treat on consecutive days will be able to treat non-consecutively within 400 days after the first one-hour treatment period. If the device is not used for a 12 hour period, the treatment clock will automatically reset and be ready to deliver the next 10 hour therapeutic treatment period when next turned on.

• Non-consecutive treatment period

(Example): On Monday, the patient treats for seven hours and turns the device off. Patient does not treat on Tuesday. Wednesday, patient turns controller on. System will be ready to treat for a full 10 hours, not the remaining three from Monday's period. Device usage log will record a seven hour treatment and a day of no treatment.

The maximum recommended therapeutic treatment period is nine months (approximately 270 days).

***Note:**

- The control unit should be turned off when finished with the treatment session
- When ready to resume treating, turn the control unit on. The display will indicate the treatment time that has been completed and keeps track of the cumulative treatment time for the day
- If the patient does not finish ten hours in that day, then use the RESET button to return the time to zero

For convenience, the daily treatment time is displayed continuously in hours and minutes. After ten hours of treatment, the display will read “10:00”, and beep three (3) times, and then shut off automatically.

ATTENTION: This is a single patient use device, do not reuse. For Prescription Use Only. The Biomet® EBI Bone Healing System is a durable therapeutic electrical device intended for single patient use only under a prescription. Treatment at home or in another appropriate or similar setting is acceptable. The device cannot be reprocessed, refurbished, disinfected, resold, sterilized, etc. with the intent to be used by another patient or for treatment other than initially prescribed.

This device has been designed to reduce the risk of potential reuse by automatically ceasing to function in accordance with the General Treatment Instructions specified and defined within.

Recommended Concurrent Fracture Treatment

The Biomet® EBI Bone Healing System works best when motion of the fracture site is minimized or nonexistent. This immobilization is achieved by applying a well molded plaster or synthetic cast at the beginning of treatment

(together with initial non-weight bearing if it is treating the lower extremity.)

- Ankle/Tarsals/Metatarsals: short leg cast or rigid internal fixation
- Tibia: stable internal or external fixation, or long leg cast (short leg cast with rigid fixation)
- Shoulder/Clavicle: brace or abduction splint, internal fixation, or figure eight immobilization
- Humerus: stable internal fixation and/or adequate immobilization with controlled rotation
- Scaphoid/Wrist: stable internal fixation or long arm cast with thumb spica (short arm cast with rigid fixation)
- Carpals/Metacarpals/Phalanges: cast, internal, or external fixation

Operating Instructions

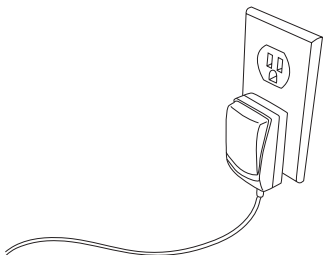
Before using the Biomet® EBI Bone Healing System for the first time, the permanently installed battery housed within the control unit must be fully charged.

Step 1: Battery Charging

The Biomet® EBI Bone Healing System operates on a lithium ion battery. Before treating with the system, the patient must fully charge the battery. At room temperatures, (24°C [75°F]) charging may take up to three and one-half hours.

Controller

A. Plug the AC Adapter into an AC wall outlet.



B. Connect the AC Wall Adapter to the Controller. The orange light on the side of the Controller will illuminate while in charging mode.

C. Unplug the AC Wall Adapter from the wall outlet and disconnect it from the Controller, after charging is complete.

***NOTE:** During battery charging, it is normal for the controller to exhibit a moderate increase in operating temperature. Once the battery is at full capacity, battery charging automatically stops and the controller will return to an ambient state.

***NOTE:** For battery charging and recharging in countries outside the USA with different power grid requirements, the plug blades should be replaced on the charger adapter to conform to local power grid requirements.

Battery Safety Warning

CAUTION: The Biomet® EBI Bone Healing System control unit contains a permanently installed Lithium Ion battery and cannot be replaced by a service technician. You must read and follow these safety instructions and warnings in conjunction with the Important safeguards provided within this manual before using or charging the battery within your control unit.

- Do not attempt to open the control unit to access the battery or its internal electronic components for any reason. No unauthorized modification of the control unit is allowed.
- Never attempt to change, adjust or reverse the battery's polarity connections for any reason.
- Do not allow or permit the control unit or its permanently installed battery to be physically mishandled, abused, crushed, mutilated or penetrated by any metal object such as a nail.
- Never allow or permit any metal object to touch or contact the permanently installed battery's terminals.
- Never store the control unit or charge the battery in extreme temperatures.
- Never charge the battery unattended.
- Always keep the control unit away from children.

Any abuse or misuse to the control unit or its permanently installed battery may result in serious personal injury and/or property damage.

Biomet® is not liable for any such abuse, misuse or resulting damage.

To ensure proper charging, **ONLY USE** the AC Wall Adapter supplied with your device system and follow the specific operating instructions provided within this manual.

Always keep the control unit and its permanently installed battery dry.

When all treatment has been completed, the control unit and permanently installed battery

Battery Safety Warning (continued)

MUST BE disposed of properly. In the USA, disposal information may be obtained by contacting the *Rechargeable Battery Recycling Corporation Hotline (RBRC)* at 1-800-822-8837. Please contact local recycling authorities for proper disposal information and instructions if outside the USA.

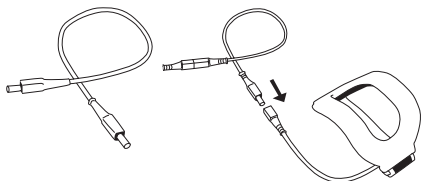
Never dispose in normal household waste or refuse.

Normal charging temperature range is 50°F (10°C) to +95°F (35°C).

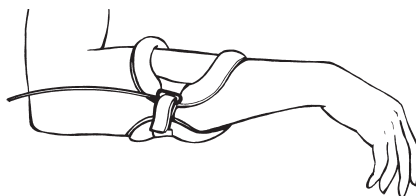
Step 2: Preparing the System to Begin Treatment

The Biomet® EBI Bone Healing System includes two link cables: “zero” length and 28". The cable exiting the controller is 4 1/2" long. All SFLX Treatment Coils have an 8" cable. Hence, use of the “zero” length link cable would separate the stimulator controller from the treatment coil by approximately 14". Use of the 28" link cable would separate the controller and treatment coil by approximately 41". A link cable of 48" is available from Biomet as a replacement part. (See ordering information page 24.) The 48" and 28" link cables cannot be used with the SFLX 5 treatment coil.

***NOTE:** The Biomet® EBI Bone Healing System is not compatible with the FLX® Coils used with the EBI Bone Healing System® – Model 2001.



After confirming that the link cable is properly connected to the controller, connect the other end of the link cable to the SFLX Flexible Treatment Coil. This connection allows for simple quick disconnect and reconnect by the patient.



Next, position the SFLX Flexible Treatment Coil over the fracture nonunion site. The entire fracture nonunion site should be centered within the coil treatment window. During treatment, the position of the treatment coil may shift due to patient activity. The treatment coil must be adjusted and centered as required to cover the fracture nonunion site.

Step 3: Treating and Charging

Patients may treat with the system while recharging the battery. When the patient treats and charges at the same time, the treatment time and charging message will be displayed.

To treat and charge, patients should:

1. Turn the control unit on.
2. Follow instructions Step 1, (Page 8) - Controller

***NOTE:** If treating while the controller unit is connected to the AC Adapter, the display will read, “TREATING 00:00 BATTERY CHARGING”. Once the patient has completed the treatment, they should turn the controller off, and leave it connected to the AC Adapter to continue charging the battery, until the LED changes from orange to green.

TREATING 00:00
BATTERY CHARGING

Operating Instructions (Continued)

Step 4: Recharging the Battery

The average daily treatment time supplied by the battery in the controller will vary according to the size of SFLX Treatment Coil being used. The controller will deliver a minimum of 10 hours of unsegmented continuous treatment for all treatment coils except the SFLX-4 and SFLX-5 Treatment Coils. The controller will deliver a minimum seven hour unsegmented continuous treatment with the SFLX-4 Treatment Coil and a three hour minimum unsegmented continuous treatment with the SFLX-5 Treatment Coil. At room temperatures, (24°C [75°F]) charging may take up to three and one-half hours.

After completing a daily treatment session, patients should do the following:

- A. Turn the controller off.
- B. Follow instructions A-C from Step 1. Controller (Page 8)
- C. It is not necessary to disconnect the controller from the AC Adapter charger once fully charged. The controller can remain plugged into the AC Wall Adapter until the patient's next treatment session.

***NOTE:** The controller's permanently installed battery cannot be overcharged. If the controller is plugged into the AC Adapter and the battery is fully charged, the charger will terminate the recharging process early. During the charging process the LED adjacent to the plug will remain orange and once the charging is complete the LED will turn green. Therefore, do not be concerned if the battery is inadvertently charged more than once.

When the Controller Needs Recharging

1. The display will read "Recharge Battery"; "Treatment Halted" and emit three audible beeps. Once beeping stops, the Controller will automatically shut OFF.



After daily treatment, turn the controller OFF and recharge as described in step 1: Battery Charging. (See page 8).

***NOTE:** An excessively low battery will result in no LCD display. If you are experiencing charging difficulties, please verify that all electrical connections are established. Then try charging the controller again. If you are still experiencing difficulties, contact Biomet. For a complete listing of contact information, refer to page 29.

Battery Indicator Display

The capacity of the battery is displayed during the course of treatment. Four bars indicates a full charge with three bars indicating approximately 75% charge.

California Perchlorate Label

The controller contains a permanently installed back up battery mounted on the printed circuit board that contains very small amounts of perchlorate. California law requires the following label: “Perchlorate Material – special handling may apply. See www.dtsc.ca.gov/hazardous-waste/perchlorate.” There is no special handling required by patients.

Avoid Potentially Explosive Atmospheres

Areas with potentially explosive atmospheres are often, but not always, posted and can include fueling areas, such as below decks on boats, fuel or chemical transfer or storage facilities, or areas where the air contains chemicals or particles, such as grain dust, or metal powders.

When the patient is in such an area, turn off your controller and do not charge the battery. In such areas, sparks can occur and cause an explosion or fire.

Controller Clip Holder

- The controller may be worn on a belt in a clip holder that is included in the system, or in the optional extremity band. The holder will securely hold the controller during normal treatment.
- To insert the controller into the clip holder, align the front of the controller that features the reset/backlight button facing away from the clip holder. Align the slots on the controller unit with the pair of matching tabs on the clip holder. Press the controller into the holder until the tab engages.

An audible click should be heard, thus securing the controller to the holder.

- Adjust clip holder placement to maximize patient comfort and avoid possible impacts with furniture, etc.

Keep the Bone Healing System and its accessories away from small children

These devices are not toys and may be hazardous to children. For Example:

- A choking hazard may exist for small detachable parts
- Improper use could result in exposure to a treatment signal for which the risks of exposure to children have not been established

Driving Precautions

The use of a non invasive bone healing system while driving may cause or contribute to potentially hazardous distractions. Patient should discontinue use while driving if this occurs.

Operating Instructions (Continued)

Keypad Functions

On/Off Button

Each time the ON/OFF button is pressed, an audible beep will be heard. To turn the controller on, press the on/off button one time. Pressing this button a second time for at least one second will turn the controller off. Every time the controller is turned on, the display will indicate the following sequence:

1. "RECOMMENDED USE 10 HOURS PER DAY" for the Biomet® EBI Bone Healing System.
2. "PATIENT USAGE"; "AVG HR/DAY 00:00" - This is the daily treatment average since the patient's treatment started.
3. "PATIENT USAGE"; "DAYS USED 000" - This is the total number of days of treatment.
4. "PATIENT USAGE"; "DAYS UNUSED 000" - This is the total number of days when there was no treatment.
5. "TREATING 00:00"; "BATTERY ███" - This is the cumulative number of hours of treatment in the present or previous treatment session, provided that the reset button has not been pressed (see RESET BUTTON).
6. Pressing the RESET button will result in the display reading "RESETTING..." for approximately three seconds. The display will then return to display as indicated in number five above.

- | | |
|----|-------------------------------------|
| 1. | RECOMMENDED USE
10 HOURS PER DAY |
| 2. | PATIENT USAGE
AVG HR/DAY 00:00 |
| 3. | PATIENT USAGE
DAYS USED 000 |
| 4. | PATIENT USAGE
DAYS UNUSED 000 |
| 5. | TREATING 0:00
BATTERY ███ |
| 6. | RESETTING... |

RESET and Display Backlight Button – Located on the Body of the Controller

The controller is designed with a backlight function to enhance the visibility of the LCD display in dim lighting. When pressed briefly, the display's backlight will turn on for 5 seconds. The system is designed with a reset function to allow the daily timer to be reset to zero. Should the patient not finish the ten hours of treatment in one day, he/she presses the RESET/Backlight button for two (2) beeps and the daily timer will go back to zero in preparation for the next treatment session. The treatment time will be retained on the display unless the RESET button is depressed for two audible beeps.

To avoid the accidental reset of the daily time, the RESET function has a three second delay. When pressed for more than one second, the controller will beep. To clear the time back to zero, continue holding the button until a second beep is heard (approximately three seconds). Release the RESET/Backlight button. This will clear the time back to 0:00.

Following completion of your daily treatment, you should do the following:

1. Make sure the controller is off. If you have completed 10 hours, the unit will automatically shut off. With less than 10 hours of treatment, you will need to manually turn the controller off.
2. Insert the AC Adapter charger into the controller to recharge the battery for your next treatment (see Step 1: BATTERY CHARGING page 8).

The Biomet® EBI Bone Healing System may be used at home or at work. Your patient's schedule and lifestyle will determine the best time for using the system. Many people find it convenient to treat while they are sleeping.

Troubleshooting System Messages

Allow up to one minute for the display message to change, after taking corrective action.

- **“RECHARGE BATTERY TREATMENT HALTED”** If this message appears, the battery needs to be recharged. This message will only appear during a treatment session. In order to recharge the battery and continue treatment, connect the AC Wall Adapter and turn the controller on. Refer to Step 4: (Page 10) “RECHARGING THE BATTERY”

**RECHARGE BATTERY
TREATMENT HALTED**

“Check Connectors See Manual”

This message, accompanied by audible beeps, appears when the controller is not properly connected to the SFLX Treatment Coil when the controller is turned on. The controller will turn itself off. Be sure to check all electrical connections between the controller, link cable and treatment coil. When the controller is turned back on and the message continues, check all cable connections again. If you need assistance, you should call 1.973.299.9300 and ask to speak to a Patient Support Representative. Outside the United States contact your local EBI/Biomet Distributor.

**CHECK CONNECTORS
SEE MANUAL**

“Check Coil See Manual”

This message, accompanied by three to four audible beeps, appears when the SFLX Treatment Coil is disconnected, damaged, or inappropriately flexed. The message will stay on the display until the controller turns itself off. If you need assistance, you should call 1.973.299.9300 and ask to speak to a Patient Support Representative. Outside the United States contact your local EBI/Biomet Distributor.

**CHECK COIL
SEE MANUAL**

Operating Instructions (Continued)

“Cannot Treat Call Biomet 1.973.299.9300”

This message, accompanied by three audible beeps, appears when there is a hardware problem within the controller. The message “CANNOT TREAT” will appear and alternate with “CALL BIOMET 1-973-299-9300”. If the patient needs assistance, they should call 1.973.299.9300 and ask to speak to a Patient Support Representative. Outside the United States contact your local EBI/Biomet Distributor.

CANNOT TREAT

Alternates with

**CALL BIOMET
1-973-299-9300**

“System Endpoint Call Biomet”,

When the controller’s internal timer reaches 400 days of operation from the first one hour treatment or 270 therapeutic treatments, the treatment signal is locked off. The controller’s LCD display will read “SYSTEM ENDPOINT CALL BIOMET” This message will appear every time the controller is turned on. At this point, the system should be discarded. It is recommended that the patient contact the prescribing physician indicating that they have reached this point in their treatment. See page 22 for Disposal Instructions.

**SYSTEM ENDPOINT
CALL BIOMET**

**Compliance Data Software Introduction
(Physician Use Only)**

This bone healing system contains embedded software and firmware which allows the display of patient-specific history data including usage and therapeutic treatment time via use of Biomet Compliance Data Download Software.

The Compliance Data Download Software is classified as a medical device data system (MDDS). Its primary function is the electronic retrieval, transfer, display, and storage of device generated-specific patient history data, without altering the function or parameters of the connected device. This software is only intended to be used and interface with the following Biomet devices:

- Biomet® EBI Bone Healing System
- Biomet® SpinalPak® Non-invasive Spine Fusion Stimulator System
- Biomet® OrthoPak® Non-invasive Bone Growth Stimulator System

The software is available as a downloadable executable file to Biomet representatives only through a secure web portal.

Patient Usage Reports (Physician Use Only)

The Compliance Data Download Software will download and transfer device-specific patient history data via a USB cable from the attached device to a personal computer (PC) and display it on the PC’s monitor. It can then generate a read-only report, in Adobe PDF format, which can be saved or printed. The device does not record a patient name or diagnosis. The analysis of the downloaded patient history data must be limited to the prescribing physician.

The print out/display includes, among other

information, days used, average hours per day, days un-used and days lapsed. Total treatment time is displayed along with a graph of the number of treatment sessions recorded at specific treatment duration hour intervals.

Care should be taken not to manipulate data in any way.

Biomet recommends patients bring their controller to each follow-up visit so that accumulated compliance data can be accessed, downloaded and reviewed by their prescribing physician at that time.

In the event patient data reveals a compliance deviation with the prescribed treatment regimen, the prescribing physician may discuss treatment options or alternatives including an evaluation regarding ongoing compliance in the patient's overall prescribed therapeutic treatment regimen.

Set-Up (Physician Use Only)

Before starting:

- 1) Obtain a USB cable for compliance download for patient history data transfer (your Biomet representative has this).
- 2) Call /Contact your local Biomet representative to arrange download of the Compliance Data Download Software.

Connect the USB Accessory cable for compliance download (PN 1067725-00) to the device's USB port located on the side of the controller to the left of the power button. Connect the USB cable to an open USB port on a PC. Turn on the device. Open the Compliance Data Download Software on the PC, and an introductory screen will appear. Follow the instructions.

Troubleshooting

If connection or printing problems occur, please check all connection cables or your network administrator. Please call Biomet (page 29) should any additional problems arise.

Warnings

The Compliance Data Download Software must only be run on a personal computer operated by or under the guidance and supervision of a Biomet sales representative. This software is only intended to be used with the following Biomet devices:

- Biomet® EBI Bone Healing System
- Biomet® SpinalPak® Non-invasive Spine Fusion Stimulator
- Biomet® OrthoPak® Non-invasive Bone Growth Stimulator System

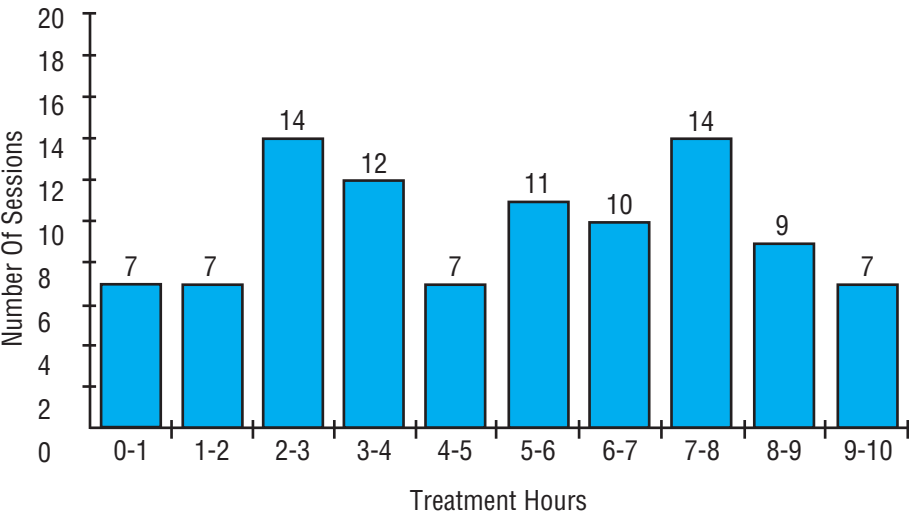
Sample

Patient Usage Report

Device: Biomet® EBI Bone Healing System

Serial Number:	0002	Days Lapsed:	1
Days Used:	78	Days Unused:	21
Avg Hours / Day:	4:13	Avg Hours / Session:	6:22
Total Treatment Time:	417 Hours	Treatment Period:	123 Days

Frequency of Treatment Dose



Demonstration mode – Invalid Data

Depth of Penetration Specifications for SFLX Treatment Coils
SFLX 1, 2, 3, 4, 5, and Coilette Treatment Coils Tolerances

SFLX Coil		M/L Flexion	Depth of Penetration	Vertical Fracture Length	Anatomical Location(s)
SFLX Mini Coilette	Minimum	2.5 cm	2.5 cm	1.5 cm	phalanges
	Maximum	3.5 cm	2 cm	1.5 cm	
SFLX Coilette	Flat	N/A	2.75 cm	4 cm	clavicle, metatarsals, scaphoid, distal radius, cuboid, medial lateral malleolus
	Elliptical	N/A	3.5 cm	4 cm	
	Saddle	N/A	3.5 cm	2 cm	
SFLX XL	Flat	N/A	3.5 cm	6 cm	foot, hand, small bones
Coilette	Elliptical	5 cm	4.25 cm	4 cm	
	Saddle	7.5 cm	5.5 cm	4 cm	
SFLX 1	Minimum	9 cm	6.5 cm	7 cm	metatarsals, scaphoid, metacarpals, radius, ulna
	Maximum	13 cm	5.5 cm	6 cm	
SFLX 2	Minimum	8 cm	8 cm	10 cm	humerus, tibia, fibula, radius, ulna
	Maximum	11 cm	7 cm	10 cm	
SFLX 2-1 (Elliptical)	Minimum	10 cm	5 cm	16 cm	tibia, fibula, radius, ulna, humerus
	Maximum	12 cm	4.5 cm	14 cm	
SFLX 2-1 (Saddle)	Minimum	8 cm	8 cm	10 cm	tibia, fibula, radius, ulna, humerus
	Maximum	11 cm	7 cm	10 cm	
SFLX 2-4	Minimum	8 cm	8 cm	10 cm	ankle
	Maximum	11 cm	7 cm	10 cm	
SFLX 3	Minimum	5 cm	7 cm	7 cm	radius, ulna, metatarsals, distal tibia/fibula
	Maximum	9 cm	5.5 cm	6 cm	
SFLX 4	Minimum	9.25 cm	10 cm	12 cm	midshaft femur, tibia, fibula, humerus
	Maximum	14.5 cm	8 cm	8 cm	
SFLX 4-1 (Saddle)	Minimum	9.25 cm	10 cm	12 cm	tibia, fibula, humerus, radius, ulna
	Maximum	14.5 cm	8 cm	8 cm	
SFLX 4-1 (Elliptical)	Minimum	12 cm	6 cm	22 cm	tibia, fibula, humerus, radius, ulna
	Maximum	14 cm	6 cm	18 cm	
SFLX 4-4	Minimum	9.25 cm	10 cm	12 cm	ankle
	Maximum	14.5 cm	8 cm	8 cm	
SFLX 5	Minimum	13 cm	12 cm	10 cm	femur (proximal or midshaft)
	Maximum	20 cm	10 cm	10 cm	

SFLX Treatment Coils (Continued)

***NOTE:** The Biomet® EBI Bone Healing System does not include a treatment coil. The prescribing physician and Biomet representative will select the treatment coil suitable for the particular part of the patient's anatomy to be treated. If initially treating with a cast treatment coil can be interchanged in the event a cast is removed. Contact your Biomet Representative for a suitable replacement. The 48" and 28" link cables cannot be used with the SFLX-5 Treatment Coil.

All SFLX Coil – Anatomical placement instructions and Flexion Gauges are included with the coil.

Specialty treatment coils are for applications where the standard straps may not be adequate to secure the treatment coil. Each specialty SFLX Treatment Coil features one (1) snap at all four corners of the coil and comes pre-assembled to fit the right side of the body, but the same snaps and straps may be easily switched for left side applications.

Application Instructions for the SFLX-1, SFLX-2, SFLX-3, SFLX-4 and SFLX-5 Treatment Coils

Applies to:

Description	Treatment Coil #	Suggested Placement*
SFLX-1	1068225	Metatarsals, Radius, Ulna, Scaphoid, Metacarpals
SFLX-2	1068226	Humerus, Tibia, Fibula, Radius, Ulna
SFLX-3	1068229	Radius, Ulna, Metatarsals, Distal Tibia/Fibula
SFLX-4	1068235	Midshaft Femur, Tibia/Fibula, Humerus
SFLX-5	1068224	Femur – Proximal or Mid Shaft

***NOTE:** Given certain anatomic locations, treatment coils may have a tendency to migrate away from the intended treatment area. Often this movement is associated with patient activity, mobility or the underlying surface the treatment coil rests on (skin, shirt, cast, etc.). The treatment coil strap(s) may be loosened and the treatment coil must be adjusted and centered as required to cover the fracture nonunion site. Tighten the straps again to finish the correction.

*Anatomic locations are suggested based on treatment coil size and configuration. The selection of a suitable treatment coil is individual to each patient and should take into account factors such as activity level, presence of a cast, patient body mass index (BMI), etc.

The SFLX Treatment Coil is chosen by the prescribing physician and Biomet representative based upon the anatomical location of the fracture nonunion, the vertical length of the fracture nonunion, the field of coverage required to treat the fracture nonunion and the physical size of the patient.

***NOTE:** Included with each treatment coil are anatomical specific placement instructions and a Flexion Gauge for measuring the tolerances of the coil. The coil should not be flexed beyond the Flex Range of the gauge (the area indicated by green color).

Flexion Gauge Instructions for SFLX-1, SFLX-2, SFLX-3, SFLX-4 and SFLX-5 Treatment Coils

In order to ensure proper fit and efficacious treatment the Flexion Gauge should be employed to check for the proper shape.

- 1) Place the treatment coil at the fracture nonunion site and shape for best fit. The Treatment Coil should be bent only in one direction. Do not kink or twist the coil.
- 2) Remove the shaped treatment coil and place edge closest to the connector cable into the slot/notch on the right hand side of the Flexion Gauge marked with a green triangle. The opposite treatment coil edge should fall within the green zone in the area marked "FLEXION RANGE". Each Flexion Gauge has a chart of treatment coil tolerances with depth of penetration data.
- 3) If the treatment coil edge does not fall within the green zone contact your Biomet representative for a suitable replacement and assistance.

Conforming the SFLX Treatment Coil

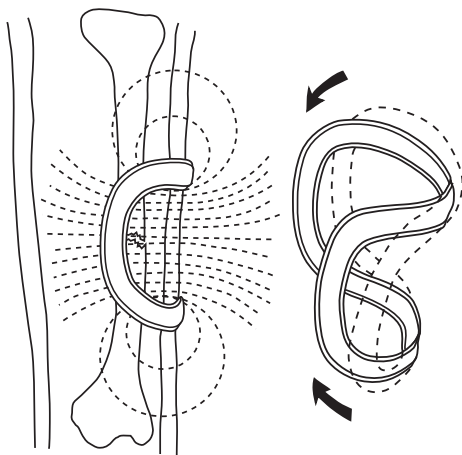
The SFLX Treatment Coil is conformable so it may be shaped directly to the surface anatomy of the fracture nonunion site being treated.

The coil is also rigid enough to retain its shape once conformed. The coil's lightweight, low, flat profile makes the treatment coil easy to apply and comfortable for the patient to wear.

The treatment coil is designed to be bent in one direction (single plane, see illustration) only. It should not be twisted or kinked.

SFLX Treatment Coil Applications

It is imperative that the entire fracture nonunion site receive a therapeutic pulsing field. This is accomplished by placing the treatment coil over the fracture nonunion site. Ensure that the entire site is centered within the treatment coil window/field of coverage.

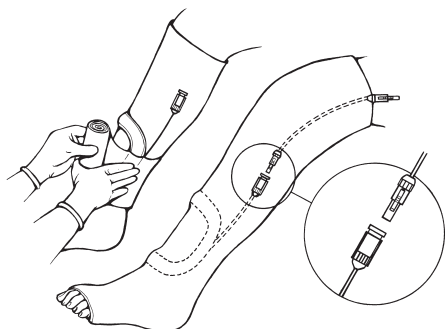


***NOTE:** During treatment, the position of the treatment coil may shift due to patient activity. The treatment coil strap(s) may be loosened and the coil adjusted and centered as required to cover the fracture nonunion site. Tighten the straps again to finish the correction.

Casted and Noncasted Applications

Casted Applications:

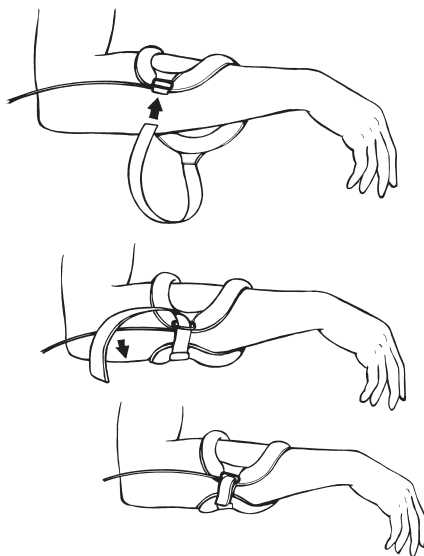
1. Apply one to two rolls of casting material (synthetic or plaster) in the usual manner, and allow it to set. Center the SFLX Treatment Coil over the fracture nonunion site, confirming correct placement with an X-ray if necessary.
2. Incorporate the SFLX Treatment Coil into the cast with an additional wrap of casting material.
3. Position the connector mounting assembly near the SFLX Treatment Coil and incorporate it into the cast with additional cast material.



***NOTE:** If patient compliance with the system is not a concern, the treatment coil may be placed on top of a cast or brace. Be sure to mark the treatment coil placement with an indelible marker for easy refitting by the patient.

Noncasted Applications:

1. Position the SFLX Treatment Coil over the fracture nonunion site. The entire fracture nonunion site should be centered within the treatment coil window/field of influence.
2. Attach and secure the SFLX Treatment Coil around the extremity with the Velcro[®] strap or the garment to give the patient a snug yet comfortable fit.



***NOTE:** To allow flexibility in anatomic coverage and positioning, the treatment coils are available in multiple sizes and configurations. It is recommended that the center of the Treatment Coil be positioned over the fracture nonunion site.

***NOTE:** During treatment, the position of the treatment coil may shift due to normal patient activity. If this occurs, the treatment coil strap(s) may be loosened to allow the coil to be adjusted and centered as required to cover the fracture nonunion site. Tighten the straps again to finish the adjustment.

Cleaning Instructions

Biomet® EBI Bone Healing System

The controller and AC Wall Adapter can be cleaned by wiping with a damp cloth and mild soap. Do not immerse in water or use solvents or other cleaning agents. **DO NOT MACHINE WASH OR DRY**

SFLX Treatment Coils

SFLX coils are not sterile. Clean with mild soap and water by wiping with a damp cloth. Do not immerse in any liquid.

***NOTE:** Please make sure the controller is disconnected from the AC Wall Outlet before cleaning.

Treatment Completion

Biomet® EBI Bone Healing System

The maximum recommended therapeutic treatment period is nine months (approximately 270 days).

When the Control Unit reaches system endpoint, the signal is locked. "SYSTEM ENDPOINT CALL BIOMET" will appear on the LCD display. The display will then turn OFF. This message will appear every time the Control Unit is turned ON. At this point, the system should be disposed of in an environmentally safe manner. (See Disposal/Recycling on page 22).

***NOTE:** If the prescribing physician feels that treatment with the Biomet® Bone Healing System is still necessary after the System Endpoint has been reached, please contact Biomet for instructions and procedure to replace the expired controller.

Equipment Classification





















- Biomet® EBI Bone Healing System
Class II
Type BF
- Ordinary equipment without protection against ingress of water
- Equipment not suitable for use in presence of flammable anaesthetic mixture with air or with oxygen or with nitrous oxide
- Mode of operation – continuous

Disposal/Recycling

The control unit, AC Wall adapter, link cables, SFLX Treatment Coil are regulated and should be properly disposed of or recycled according to local statutes and regulations. Please contact your local recycling center for instructions and procedures to safely dispose of the Biomet® EBI Bone Healing System.

WARNING: Never dispose of control unit in a fire because it contains a permanently installed battery which could explode.

Symbol Description

	Warning
	Note
	Type BF Equipment
	Direct Current
	Alternating Current
	Attention – See Instructions
	Non-ionizing Radiation
	Class II
	Single Patient Use / Single Prescription
	WEEE – Do not dispose of this device with household waste
	Charge Battery
	Reset
	Backlight
	On/Off
Rx Only	Prescription Only
	Manufacturer
	Not for use by patients who are pregnant or becoming pregnant
	Not recommended for patients with certain types of pacemakers or implantable defibrillators
	Temperature range for storage and transportation
 Li-ION	Lithium Ion Battery – Recycle in compliance with local laws
	The Biomet® EBI Bone Healing System has not been tested for safety or been evaluated for heating in the MR environment.

Ordering Information

To order replacement treatment coils or related components contact your Biomet representative or call the Biomet Patient Support Department directly at 1.973.299.9300, 8:30 A.M. to 5:30 P.M. Eastern Time Monday through Friday. Outside the United States contact your local EBI/Biomet Distributor.

The Following Information is Necessary to Expedite Any Requests:

- Patient name
- Prescribing Physician name
- Where to send replacement items (patient home, MD office, etc.)
- Available component parts: (See page 24)

References

C.A.L. Bassett, Robert J. Pawluk, and A.A. Pilla. "Augmentation and Bone Repair by Inductively Coupled Electromagnetic Fields". *Science* 184:575-577, 1974.

C.A.L. Bassett, S.N. Mitchell, L. Norton, N. Caulo and S.R. Gaston. "Electromagnetic Repairs of Non-Unions. Electrical and Magnetic Control of Musculoskeletal Growth and Repair". C.T. Brighton, ed., *Grune and Stratton*, New York, 1979.

C.A.L. Bassett, S.N. Mitchell, and S.R. Gaston. "Treatment of Ununited Tibial Diaphyseal Fractures With Pulsing Electromagnetic Fields". *Journal of Bone and Joint Surgery* Vol. 63-A, No. 4, pp. 511-523, April, 1981.

C.A.L. Bassett, S.N. Mitchell, and S.R. Gaston. "Pulsing Electromagnetic Field Treatment in Ununited Fractures and Failed arthrodeses". *Journal of the American Medical Association* Vol. 247, No. 5, pp. 623-628, February 5, 1982.

C.A.L. Bassett, Pulsing Electromagnetic Fields: "A New Method to Modify Cell Behavior in Calcified and Non-Calcified Tissue". *Calcified Tissue*, Int. Vol. 34, No. 1:1-8, 1982.

Biomet® EBI Bone Healing System Components

Replacements and Components

Catalog #	Description
1068234	Controller Assembly – USA
1068233	Controller Only RP
1068208	Clip Holder RP
1068209	Extremity Band
1068222	Belt Strap RP
1068315	AC Wall Adapter RP – USA
1068225	SFLX 1 Coil
1068226	SFLX 2 Coil
1068227	SFLX 2-1 Coil
1068228	SFLX 2-4 Coil
1068229	SFLX 3 Coil
1068235	SFLX 4 Coil
1068236	SFLX 4-1 Coil
1068237	SFLX 4-4 Coil
1068224	SFLX 5 Coil
1068238	SFLX - Coilette
1068239	SFLX - Mini Coilette
1068240	SFLX - XL Coilette
1068210	Cable “Zero” Inch RP
1068215	Cable 28" RP
1068223	Cable 48"
1068313	Black Velcro ⁺ Strapping For SFLX Treatment Coilette
1068314	Black Velcro ⁺ Strapping For SFLX Treatment Coilette – Clavicle Application
1068317	International Wall Plug Blade Adapter Kit

RP = Replacement Part

Accessories

Catalog #	Description
1067725-00	USB Cable For Compliance Download

Electromagnetic Compatibility

- The use of accessories and cables other than those supplied may result in increased emissions or decreased immunity of the equipment or system
- This equipment should not be used adjacent to or stacked upon other equipment
- Portable and mobile RF communications equipment can adversely affect the operation of Medical Electrical Equipment
- In the event this equipment interferes with the operation of other equipment, or experiences interference from other equipment, to continue treatment it will be necessary to move the Biomet® EBI Bone Healing System away from the source of the interference as indicated in table 4

Table 1

Guidance and Manufactures Declaration – Electromagnetic Emissions

The Biomet® EBI Bone Healing System is intended for use in the electromagnetic environment specified below. The customer or the user of the Biomet® EBI Bone Healing System should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions CISPR 11	Group 1	The Biomet® EBI Bone Healing System must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF Emissions CISPR 11	Class B	The Biomet® EBI Bone Healing System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Not Applicable	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	Not Applicable	

Electromagnetic Compatibility (Continued)

Table 2

Guidance and Manufactures Declaration – Electromagnetic Immunity


The Biomet® EBI Bone Healing System is intended for use in the electromagnetic environment specified below. The customer or the user of the Biomet® EBI Bone Healing System should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic Discharge (ESD) IEC 610004-2	± 6 kV contact ± 8 kV air		Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient/Burst IEC 610004-4	± 2 kV for power supply lines ± 1 kV for input/output lines		Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 610004-5	± 1 kV for differential mode ± 2 kV for common mode		Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% UT (> 95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles < 5% UT (> 95% dip in UT) for 5 sec		Mains power quality should be that of a typical commercial or hospital environment. If the user of the Biomet® EBI Bone Healing System requires continued operation during power mains interruptions, it is recommended that the Biomet® EBI Bone Healing System be powered from an uninterruptible power supply (UPS).
Power frequency (50/60 Hz) magnetic field	3 A/m		Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Table 3

Guidance and Manufactures Declaration – Electromagnetic Immunity

The Biomet® EBI Bone Healing System is intended for use in the electromagnetic environment specified below. The customer or the user of the Biomet® EBI Bone Healing System should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	3 Vrms	1 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the Biomet® EBI Bone Healing System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended Separation Distance $d = 3.5 \sqrt{P}$ $d = 3.5 \sqrt{P}$ 80 MHz to 800 MHz $d = 7 \sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum power output rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, ^a should be less than the compliance level in each frequency range. ^b Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated-4-6 IEC 61000-4-3	3 V/m	1 V/m	
	80 MHz to 2.5 GHz		

NOTE 1. At 80 MHz and 800 MHz, the higher frequency applies.

NOTE 2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

- a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Biomet® EBI Bone Healing System is used exceeds the applicable RF compliance level, the Biomet® EBI Bone Healing System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Biomet® EBI Bone Healing System.
- b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 1 V/m.

Table 4
Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Biomet® EBI Bone Healing System

The Biomet® EBI Bone Healing System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Biomet® EBI Bone Healing System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile communications equipment (transmitters) and the Biomet® EBI Bone Healing System as recommended below, according to the maximum power output of the communications equipment.

	Separation Distance (Meters) According to Frequency of Transmitter		
Rated Maximum Output Power of Transmitter W	150 kHz to 80 MHz $d = 3.5 \sqrt{P}$	80 MHz to 800 MHz $d = 3.5 \sqrt{P}$	150 MHz to 2.5 GHz $d = 7 \sqrt{P}$
.01	.35	.35	.7
.1	1.1	1.1	2.21
1	3.5	3.5	7
10	11.06	11.06	22.13
100	35	35	70

For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

- NOTE 1.** At 80 MHz and 800 MHz, the separation distance for the higher frequency applies.
- NOTE 2.** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people

Further Information

Biomet

399 Jefferson Road

Parsippany, New Jersey 07054

1.973.299.9300

If you are a patient and need to contact
Biomet, please use the following numbers:

Ordering Replacements

- Patient Services Department
- 1.973.299.9300

Returns/Defective Products/ Troubleshooting

- Quality Assurance Department
- 1.973.299.9300

Questions About Your Bill

- Patient Advocacy Department
- Phone: 1.888.236.3652 (USA only)
- e-mail: patientadvocate@biomet.com

Reimbursement Form

CPT Code 20974
Electrical Stimulation to Aid Bone
Healing: Non-Invasive (Non-Operative)

From a CPT perspective, an additional evaluation and management service (E/M - office visit code) is generally not payable; unless

- the physician is providing a significant, separately identifiable E/M service beyond the noninvasive electrical bone stimulation; or,
- beyond the usual postoperative care associated with the procedure(s) performed; and,
- the physician is providing and meeting the three, key components (e.g., history, examination and medical decision making).

Once these additional requirements are met, then the appropriate level of E/M service with the modifier-25 amended, may be reported in addition to CPT code 20974.

CPT 20974 is exempt from the use of modifier-51 (multiple procedures) for services performed on the same day or at the same session by the same provider.

Reimbursement Coding Note
CPT 20974 - Electrical Stimulation to
Aid Bone Healing (Non-Invasive)

(CPT Code 20974 is considered to be a minor procedure with a global day “000” designation)

A Biomet Stimulator has been applied as follows:

Patient_____

Fracture/Fusion Site_____

Physician_____

Date_____

Physician Management of Biomet Stimulators are generally recognized under CPT code 20974. This code encompasses services associated with the initial patient evaluation for stimulation, application and follow-up assessment related to the treatment system. (Global period for primary procedure remains the same.)

Please note that from a CPT perspective, office visits (E&M - Evaluation and Management Codes) are generally not payable when provided on the same day of service as 20974.

Notes: _____

31

Notes: _____

32

OPTIONS

The industry's most comprehensive options:

- PEMF, CC and DC
- Anatomy specific coils
- Wear-time choice

EVIDENCE

- Backed by proven science
- Multiple scientific papers

EXPERIENCE

Recognized as an industry pioneer with EBI lineage, Biomet has helped over one million people



Biomet® EBI Bone Healing System

Physician Manual and Package Insert
English Language

To learn more about this product,
contact your local Biomet Sales Representative today.



399 Jefferson Road, Parsippany, NJ 07054

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